

[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: Use of the CD47

**Phosphorodiamidate Morpholino Oligomers for the Treatment, Prevention, and
Diagnosis of Solid Tumors**

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Cancer Institute, an institute of the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an Exclusive Patent License to practice the inventions embodied in the Patents and Patent Applications listed in the Supplementary Information section of this notice to Morphix Biotherapeutics (“Morphix”) located in Boston, MA.

DATES: Only written comments and/or applications for a license which are received by the National Cancer Institute’s Technology Transfer Center on or before **[INSERT DATE 15 DAYS FROM DATE OF PUBLICATION OF NOTICE IN THE *FEDERAL REGISTER*]** will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, and comments relating to the contemplated an Exclusive Patent License should be directed to: Jaime Greene, Senior Licensing and Patenting Manager, NCI Technology Transfer Center, 9609 Medical Center Drive, RM 1E530 MSC 9702, Bethesda, MD 20892-9702 (for business mail), Rockville, MD 20850-9702 Telephone: (240)-276-5530; Facsimile: (240)-276-5504 E-mail: greenejaime@mail.nih.gov.

SUPPLEMENTARY INFORMATION:

This is in reference to a previous notice 83 FR 22501, which was a Prospective Grant of an Exclusive Patent License to Morphix for the field of use “the use of the CD47 phosphorodiamidate morpholino oligomers (PMO, morpholino, Sequence: 5'-CGTCACAGGCAGGACCCACTGCCCA-3') for the treatment, prevention, and diagnosis of hematological cancers (e.g. lymphoma, leukemia, multiple myeloma), excluding uses in combination with radiotherapy.”

Intellectual Property

1. U.S. Provisional Patent Application No. 60/850,132, filed October 6, 2006, now abandoned (HHS Ref. No. E-227-2006/0-US-01);
2. U.S. Provisional Patent Application No. 60/864,153, filed November 02, 2006, now abandoned (HHS Ref. No. E-227-2006/1-US-01);
3. U.S. Provisional Patent Application No. 60/888,754, filed February 07, 2007, now abandoned (HHS Ref. No. E-227-2006/2-US-01);
4. U.S. Provisional Patent Application No. 60/910,549, filed April 06, 2007, now abandoned (HHS Ref. No. E-227-2006/3-US-01);
5. U.S. Provisional Patent Application No. 60/956,375, filed August 16, 2007, now abandoned (HHS Ref. No. E-227-2006/4-US-01);
6. PCT Patent Application No. PCT/2007/080647, filed October 5, 2007, now abandoned (HHS Ref. No. E-227-2006/5-PCT-01);
7. U.S. Patent No. 8,236,313, filed April 3, 2009, Issued August 7, 2012 (HHS Ref. No. E-227-2006/5-US-02);
8. Canadian Patent Application No. 2,665,287, October 5, 2007 (HHS Ref. No. E-227-2006/5-CA-03);
9. Australian Patent No. 2007319576, filed October 5, 2007, Issued May 1, 2014 (HHS Ref. No. E-227-2006/5-AU-04);
10. European Patent Application No. 07868382.8, filed March 27, 2009 (HHS Ref. No. E-227-2006/5-EP-05);
11. U.S. Patent Application No. 13/546,931, filed July 11, 2012 (HHS Ref. No. E-227-2006/5-US-06);
12. U.S. Patent Number 8,557,788, filed July 11, 2012, Issued October 15, 2013 (HHS Ref. No. E-227-2006/5-US-07);
13. European Patent Application No. 13180563.2, filed October 5, 2007 (HHS Ref. No. E-227-2006/5-EP-08);

14. Australian Patent No. 2014201936, filed October 5, 2007, Issued October 20, 2016 (HHS Ref. No. E-227-2006/5-AU-09);
15. U.S. Patent Application No. 14/500,861, filed September 29, 2014 (HHS Ref. No. E-227-2006/5-US-10);
16. Australian Patent No. 2016238894, filed October 6, 2016, Issued February 22, 2018 (HHS Ref. No. E-227-2006/5-AU-11); and
17. Australian Patent Application No. 2018200921, filed February 8, 2018 (HHS Ref. No. E-227-2006/5-AU-12).

The patent rights in these inventions have been assigned and/or exclusively licensed to the government of the United States of America.

The prospective exclusive license territory may be worldwide, and the field of use may be limited to: “The use of the CD47 phosphorodiamidate morpholino oligomers (PMO, morpholino, Sequence: 5’-CGTCACAGGCAGGACCCACTGCCCA-3’) for the treatment, prevention, and diagnosis of solid tumors, excluding uses in combination with radiotherapy.”

This technology concerns CD47, originally named integrin-associated protein, which is a receptor for thrombospondin-1 (TSP1), a major component of platelet α -granules from which it is secreted on platelet activation. A number of important roles for CD47 have been defined in regulating the migration, proliferation, and survival of vascular cells, and in regulation of innate and adaptive immunity. Nitric Oxide (NO) plays an important role as a major intrinsic vasodilator, and it increases blood flow to tissues and organs. Disruption of this process leads to peripheral vascular disease, ischemic heart disease, stroke, diabetes and many more significant diseases. The inventors have discovered that TSP1 blocks the beneficial effects of NO and prevents it from dilating blood vessels and increasing blood flow to organs and tissues. Additionally, they discovered that this regulation requires TSP1 interaction with its cell receptor, CD47. These inventors have also found that blocking TSP1-CD47 interaction through the

use of antisense morpholino oligonucleotides, peptides or antibodies have several therapeutic benefits including the treatment of cancer.

This notice is made in accordance with 35 U.S.C. 209 and 37 CFR Part 404. The prospective exclusive license will be royalty bearing, and the prospective exclusive license may be granted unless within fifteen (15) days from the date of this published notice, the National Cancer Institute receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR Part 404.

In response to this Notice, the public may file comments or objections. Comments and objections, other than those in the form of a license application, will not be treated confidentially, and may be made publicly available.

License applications submitted in response to this Notice will be presumed to contain business confidential information and any release of information in these license applications will be made only as required and upon a request under the Freedom of Information Act, 5 USC 552.

Dated: December 18, 2018.

Richard U. Rodriguez,

Associate Director,

Technology Transfer Center,

National Cancer Institute.

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